CalREDIE ELR
Guidance Document for Title 17, Section 2505 Changes
September 2019

The California Department of Public Health (CDPH), in consultation with the California Conference of Local Health Officers (CCLHO), recently updated Title 17, Section 2505 of the California Code of Regulations (CCR). A full description of the changes can be found in the attached letter titled '2019 Title 17 2505 Changes – Letter to Laboratories' and the updated 2505 list of reportable diseases and conditions can be found here: Lab Reportable Diseases (PDF). These changes go into effect October 1, 2019.

This document provides implementation guidance for CalREDIE ELR submitters to meet the new reporting requirements. Section 1 includes information on how to include the newly required data elements in ELR HL7 2.5.1 messages and Section 2 includes information on which laboratory results for the newly reportable disease conditions should be reported. Questions about this document can be sent to calrediehelp@cdph.ca.gov.

Section 1: New Data Elements to Include in ELR messages:

The following data elements are now required to be included:

- Pregnancy Status (required for all patients, reports and diseases)
- Diagnosis code
- Specimen Site

Pregnancy Status

- Use OBR-13 to indicate pregnancy status.
    - If the patient's pregnancy status is **NOT pregnant**, populate OBR-13 with 'Not pregnant'.
    - If the patient's pregnancy status is **pregnant**, populate OBR-13 with 'Prenatal'.
    - If the patient's pregnancy status is **unknown**, populate OBR-13 with 'Unknown pregnancy'.
- See page 100 of the CalREDIE HL7 2.5.1 ELR2PH Companion Guide for additional guidance. Email calrediehelp@cdph.ca.gov to request a copy of the Companion Guide.
    - Comments: Use length of 1..300=

Diagnosis Code

- Only ICD-10 codes submitted with the test requisition and related to the test being reported should be populated in OBR-31.
- See page 111 of the CalREDIE HL7 2.5.1 ELR2PH Companion Guide for additional guidance. Email calrediehelp@cdph.ca.gov to request a copy of the Companion Guide.
- Comments:

- Assume the standard code populates the first triplet and the local code the second. This element can repeat. This code will be drawn from ICD-10. **ICD-10 website:** https://www.cms.gov/Medicare/Coding/ICD10/2019-ICD-10-CM.html

Specimen Site and Specimen Source

- Specimen site refers to the anatomic location (e.g., left arm, eye, etc.) and is sent in SPM.8.
  - See page 138 of the CalREDIE HL7 2.5.1 ELR2PH Companion Guide for additional guidance. Email calrediehelp@cdph.ca.gov to request a copy of the Companion Guide.

- Specimen source (type) refers to the type or material of the specimen (e.g., blood, sputum, urine, etc.) and is sent in SPM.4.
  - See page 132 of the CalREDIE HL7 2.5.1 ELR2PH Companion Guide for additional guidance. Email calrediehelp@cdph.ca.gov to request a copy of the Companion Guide.

Section 2: New Results to be Reported via ELR:

Positive laboratory tests for the following disease conditions are now required to be reported to CalREDIE:

- Carbapenem-resistant Enterobacteriaceae (Carbapenemase-producing) (CP-CRE)
- Influenza
- Latent Tuberculosis infection (LTBI) identified by a positive laboratory test (including positive interferon gamma release assays [IGRA])
- Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

Carbapenem-resistant Enterobacteriaceae (Carbapenemase-producing) [CP-CRE]

- Submit all antimicrobial susceptibility testing (AST) results (MIC values and interpretation).
- Results should be reported electronically using clear, properly formatted parent-child relationships to tie susceptibility observations and carbapenemase identification observations to the initial organism identification observation; e.g., *Klebsiella pneumoniae* would be the parent observation, and the associated AST results would be the child observation.
  - See page 179 of the CalREDIE HL7 2.5.1 ELR2PH Companion Guide for instructions on how to format a parent-child relationship.
- Laboratories using a reference or public health laboratory for AST or carbapenemase testing must include these results in the final ELR message.

- Laboratories that are able to perform carbapenemase testing should wait until **all** tests (AST, phenotypic and/or molecular) are resulted **before** submitting the final ELR message.
- Laboratories that perform molecular carbapenemase testing should report the specific carbapenemase gene(s) identified (e.g., KPC or NDM).
- **Appendix A** includes CP-CRE LOINC and SNOMED codes for organism identification; carbapenem and other AST results; and carbapenemase detection by phenotypic and molecular methods. This list is not exhaustive.
- Laboratories **that perform carbapenemase testing**, or use a public health or reference laboratory to obtain carbapenemase testing, must report the following:

  Any *Enterobacter* spp., *Escherichia coli*, or *Klebsiella* spp. where the isolate is:
  1. Positive for carbapenemase production by a **phenotypic** method (see Table 2)
     -**OR**-
  2. Positive for a known carbapenemase resistance mechanism[1] by a recognized [**molecular**] test (see Table 2)

Table 2. Phenotypic and molecular methods for carbapenemase testing[2]

Phenotypic tests for carbapenemase production	Molecular tests for resistance mechanism
Carba NP	BioFire
Carbapenem inactivation method (CIM)	Polymerase chain reaction (PCR)
Metallo-β-lactamase test (e.g., E-test)	Verigene
Modified carbapenem inactivation method (mCIM)	Whole-genome sequencing (WGS)
Modified Hodge test (MHT)[3]	Xpert Carba-R

- Laboratories **that do <u>not</u> perform or obtain carbapenemase testing**, must report the following:

  Enterobacter spp., *Escherichia coli*, or *Klebsiella* spp. from any site, resistant to any carbapenem:

[1] *Klebsiella pneumoniae* carbapenemase (KPC), New Delhi metallo-β-lactamase (NDM), Verona integron-encoded metallo-β-lactamase (VIM), imipenemase (IMP) metallo-β-lactamase, OXA-48 carbapenemase, or novel carbapenemase

[2] Validated carbapenemase testing methods developed in the future may be added to this list.

[3] A positive MHT can be used to confirm CP-CRE for *Klebsiella* spp and *E. coli* but **not** *Enterobacter* spp. An isolate that tests positive on MHT but negative by PCR for KPC, NDM, OXA-48, VIM and IMP should have additional characterization performed with another phenotypic test for carbapenemase such as mCIM.

- Doripenem, imipenem, or meropenem (MIC ≥4 µg/ml); or ertapenem (MIC ≥2 µg/ml)

- Laboratories interested in identifying public health laboratory resources for carbapenemase testing should contact their Local Health Department.

Influenza

- Send all positive influenza results via ELR.
- Do NOT fax or send other paper-based influenza positive results unless requested to do so by the Local Health Department.

Latent Tuberculosis infection (LTBI) identified by a positive laboratory test

- All positive interferon gamma release assays (IGRA) must be reported, including QuantiFERON-TB Gold Plus (QFT-Plus) and T-SPOT.TB results.
- For each panel test, report all results together.
- **Appendix B** includes a sample of properly formatted QFT-Plus and T-Spot.TB ELR Messages
- QFT-Plus
    - Panel Code LOINC: 71775-1
    - Long Name: Mycobacterium tuberculosis stimulated gamma interferon panel – Blood

        1. Nil or Negative Control Tube (grey cap)
            - LOINC: 71776-9
            - Long Name: Gamma interferon background [Units/volume] in blood by immunoassay
        2. Mitogen or Positive Control Tube (purple cap)
            - LOINC: 71774-4
            - Long Name: Mitogen stimulated gamma interferon [Units/volume] corrected for background in blood

            *Mitogen minus nil
        3. TB Antigen (green cap TB 1)
            - LOINC: 64084-7
            - Long Name: Mycobacterium tuberculosis stimulated gamma interferon [Units/volume] corrected for background in blood

            *TB Antigen minus nil
        4. TB Antigen (yellow cap TB 2)
            - LOINC: 88517-8
            - Long Name: Mycobacterium tuberculosis stimulated gamma interferon release by helper CD4 and cytotoxic CD8 cells [Units/volume] corrected for background in blood
        5. Calculation of Positive, Negative, or Indeterminate
            - LOINC: 71773-6
            - Long Name: Mycobacterium tuberculosis stimulated gamma interferon [Presence] in blood

Interpretation Criteria for QuantiFERON-TB Gold Plus (QFT-Plus) (Adapted from QFT-Plus Package Insert)

<table>
<tr><th>Nil (IU/mL)</th><th>TB1 minus Nil (IU/mL)</th><th>TB2 minus Nil (IU/mL)</th><th>Mitogen minus Nil (IU/mL)</th><th>QFT-PLUS Result</th><th>Report/Interpretation</th><th>SNOMED CT</th></tr>
<tr><td>LOINC 71776-9</td><td>LOINC 64084-7</td><td>LOINC 88517-8</td><td>LOINC 71774-4</td><td>LOINC 71773-6</td><td></td><td></td></tr>
<tr><td rowspan="4">≤8.0</td><td>≥0.35 and ≥ 25% of Nil value</td><td>Any</td><td rowspan="2">Any</td><td rowspan="2">Positive</td><td rowspan="2">M. tuberculosis infection likely</td><td rowspan="2">10828004</td></tr>
<tr><td>Any</td><td>≥0.35 and ≥ 25% of Nil value</td></tr>
<tr><td><0.35 or ≥0.35 and <25% of Nil value</td><td><0.35 or ≥0.35 and <25% of Nil value</td><td>≥0.5</td><td>Negative</td><td>M. tuberculosis infection NOT likely</td><td>260385009</td></tr>
<tr><td><0.35 or ≥0.35 and <25% of Nil value</td><td><0.35 or ≥0.35 and <25% of Nil value</td><td><0.5</td><td rowspan="2">Indeterminate</td><td rowspan="2">Likelihood of M. tuberculosis infection cannot be determined</td><td rowspan="2">82334004</td></tr>
<tr><td>>8.0</td><td colspan="3">Any</td></tr>
</table>

- T-SPOT.TB
    - Panel Code LOINC: 74281-7
    - Long Name: Mycobacterium tuberculosis stimulated gamma interferon and spot count panel-Blood

1. Positive Control
    - LOINC: 74280-9
    - Long Name: Mitogen stimulated gamma interferon positive control spot count [#] in blood

6. Nil Control Well Count
    - LOINC: 74279-1
    - Long Name: Gamma interferon negative control spot count [#] in blood
7. Panel A Spot Count
    - LOINC: 74278-3
    - Long Name: Mycobacterium tuberculosis stimulated gamma interferon ESAT-6 Ag spot count [#] in blood
8. Panel B Spot Count
    - LOINC: 74277-5
    - Long Name: Mycobacterium tuberculosis stimulated gamma interferon CFP10 Ag spot count [#] in blood
9. Result Interpretation
    - LOINC: 71773-6
    - Long Name: Mycobacterium tuberculosis stimulated gamma interferon [Presence] in blood

Interpretation Criteria T-SPOT.TB Test

Nil Control Well Count LOINC: 74279-1	Either Panel A (LOINC: 74278-3) or Panel B (LOINC: 74277-5) has following # of spots	Result Interpretation (LOINC: 71773-6)
0	≥8	Positive
1	≥9	Positive
2	≥10	Positive
3	≥11	Positive
4	≥12	Positive
5	≥13	Positive
6	≥14	Positive
7	≥15	Positive
8	≥16	Positive
9	≥17	Positive
10	≥18	Positive
>10	n/a	Indeterminate

Note: The highest Panil-Nil spot count is to be used to determine the test outcome.

Source**:** Courtesy of Eric Haas (APHL Consultant)

Interpretation	**SNOMED CT**	**Nil*** LOINC: 74279-1	**TB Response****	**Mitogen***** LOINC:74280-9
Positive[1]	10828004	≤10 spots	≥8 spots	Any
Borderline[2]	42425007	≤10 spots	5, 6, or 7 spots	Any
Negative[3]	260385009	≤10 spots	≤4 spots	
Indeterminate[4]	82334004	>10 spots	Any	Any
		≤10 spots	<5 spots	<20 spots

Source: MMWR (2010) Based on Oxford Immunotec Limited T-Spot.TB

*Number of spots resulting from incubation of PBMCs in culture media without antigens
** The greater number of spots resulting from stimulation of PBMCs with two separate cocktails of peptides representing ESAT-6 or CFP-10 minus Nil. Electronic reporting however should be of the actual spot count of Panel A (LOINC: 74278-3) and Panel B (LOINC: 74277-5) WITHOUT subtracting the nil well spots.
***Number of spots resulting from stimulation of PBMCs with mitogen without adjustment for the number of spots resulting from incubation of PBMCs without antigens
[1] M. tuberculosis infection likely
[2] Uncertain likelihood of M. tuberculosis infection
[3] M. tuberculosis infection NOT likely
[4] Results are indeterminate

Middle East Respiratory Syndrome (MERS-CoV)

- Send all positive MERS-CoV results.

- Note: There are a limited number of laboratories that perform testing for MERS-CoV.

HIV/AIDS

- For lab reporting of HIV, reports of confirmed tests, including all tests used to monitor HIV infection such as nucleic acid, are required to go to the local health officer for the local health jurisdiction where the health care provider is located, as specified in Title 17 CCR Section 2643.10
    - HIV lab reports received via ELR will be routed in accordance with these requirements. All laboratories currently transmitting ELRs for HIV tests are in compliance and no additional action is required.
    - HIV lab reports sent by any method OTHER THAN ELR* will need to be routed to the jurisdiction where the health care provider is located.

*Fax is no longer a routine reporting option for labs, and they should be reporting via the electronic system (ELR), but if reporting to the state or local electronic reporting system is not possible, reporting by electronic facsimile transmission or electronic mail may temporarily substitute for reporting to the state or local electronic reporting system. Please contact the CalREDIE Help Desk (CalREDIEHelp@cdph.ca.gov) for information about how to get started with ELR.

Appendix A: CP-CRE LOINC and SNOMED Codes

Organism identification			
LOINC	**LOINC name**	**SNOMED**	**SNOMED name**
11475-1	Microorganism identified: Prld: PT : xxx: Nom: Culture	112283007 58683007 1485002 414102007 62592009 56415008 40886007 431976004 75032006	*Escherichia coli* *Enterobacter* organism *Enterobacter cloacae* *Enterobacter cloacae complex* *Klebsiella aerogenes* *Klebsiella pneumoniae* *Klebsiella oxytoca* *Klebsiella variicola* Genus *Klebsiella*
75757-6	Bacteria identified in Isolate by MS.MALDI-TOF	112283007 58683007 1485002 414102007 62592009 56415008 40886007 431976004 75032006	*Escherichia coli* *Enterobacter* organism *Enterobacter cloacae* *Enterobacter cloacae complex* *Klebsiella aerogenes* *Klebsiella pneumoniae* *Klebsiella oxytoca* *Klebsiella variicola* Genus *Klebsiella*

	Susceptibility results
56031-8	Doripenem [Susceptibility] by Minimum inhibitory concentration (MIC)
35801-0	Ertapenem [Susceptibility] by Minimum inhibitory concentration (MIC)
279-0	Imipenem [Susceptibility] by Minimum inhibitory concentration (MIC)
6652-2	Meropenem [Susceptibility] by Minimum inhibitory concentration (MIC)
73625-6	cefTAZidime+Avibactam [Susceptibility] by Minimum inhibitory concentration (MIC)
205-5	Colistin [Susceptibility] by Minimum inhibitory concentration (MIC)
85423-2	Eravacycline [Susceptibility] by Minimum inhibitory concentration (MIC)
85424-0	Imipenem+Relebactam [Susceptibility] by Minimum inhibitory concentration (MIC)
85427-3	Meropenem+Vaborbactam [Susceptibility] by Minimum inhibitory concentration (MIC)
73614-0	Plazomicin [Susceptibility] by Minimum inhibitory concentration (MIC)
420-0	Polymyxin B [Susceptibility] by Minimum inhibitory concentration (MIC)
42355-8	Tigecycline [Susceptibility] by Minimum inhibitory concentration (MIC)

	Carbapenemase detection methods		
86930-5	Carbapenemase [Presence] in Isolate	10828004 260385009 42425007 419984006	Positive Negative Equivocal Inconclusive
74676-8	Carbapenemase [Type] in Isolate by Carba NP	10828004 260385009 42425007 82334004	Positive Negative Equivocal Indeterminate
	Carbapenemase Detected via Carbapenem Inactivation Method (CIM)	10828004 260385009 42425007	Positive Negative Equivocal
	Carbapenemase Detected via Modified Carbapenem Inactivation Method (mCIM)	10828004 260385009 42425007 82334004	Positive Negative Equivocal Indeterminate
85502-3	Carbapenemase resistance genes panel by Molecular genetics method		

	Carbapenemase genes		
85498-4	Carbapenem resistance blaIMP gene [Presence] by Molecular method	260373001 260415000	Detected Not detected
85499-2	Carbapenem resistance blaKPC gene [Presence] by NAA with probe detection	260373001 260415000	Detected Not detected
85500-7	Carbapenem resistance blaNDM gene [Presence] by NAA with probe detection	260373001 260415000	Detected Not detected
85503-1	Carbapenem resistance blaOXA-48 gene [Presence] by Molecular method	260373001 260415000	Detected Not detected
85501-5	Carbapenem resistance blaVIM gene [Presence] by Molecular method	260373001 260415000	Detected Not detected
75686-6	bla(IMP) Ql Prb Mag	260373001 260415000	Detected Not detected
75683-3	bla(KPC) Ql Prb Mag	260373001 260415000	Detected Not detected
75684-1	bla(NDM) Ql Prb Mag	260373001 260415000	Detected Not detected
75687-4	bla(OXA) Ql Prb Mag	260373001 260415000	Detected Not detected
75685-8	bla(VIM) Ql Prb Mag	260373001 260415000	Detected Not detected
63368-5	Carbapenem resistance blaIMP gene [Presence] by Molecular method	10828004 260385009	Positive Negative

	Carbapenemase genes		
49617-4	Carbapenem resistance blaKPC gene [Presence] by Molecular method	10828004 260385009	Positive Negative
73982-1	Carbapenem resistance blaNDM gene [Presence] by Molecular method	10828004 260385009	Positive Negative
63368-5	Carbapenem resistance blaOXA-48 gene [Presence] by Molecular method	10828004 260385009	Positive Negative
63368-5	Carbapenem resistance blaVIM gene [Presence] by Molecular method	10828004 260385009	Positive Negative

Appendix B: QFT-Plus and T-Spot.TB Sample Messages

Sample HL7 message for QFT-Plus

MSH|^~\&
|… SFT|…
PID|1|…
ORC|RE|MM0036-18085 Placer_LIS^2.16.840.1.113883.3.2.12.1.99^ISO|C626069564^Filler Order Number^2.16.840.1.113883.3.2.12.1.1^ISO|…
OBR|1| MM0036-18085 Placer_LIS^2.16.840.1.113883.3.2.12.1.99^ISO|C626069564^Filler Order Number^2.16.840.1.113883.3.2.12.1.1^ISO|71775-1^M TB IGNF pnl Bld^LN^QFT4^QuantiFERON-Tb Gold Plus, B^L^^U|…
OBX|1|CE|71773-6^M TB IGNF Bld Ql^LN^QFTQ2^QuantiFERON-Tb Gold Plus Result^L^2.63^U||10828004^Positive^SCT||Negative|A^Abnormal^HL70078^A^Abnormal^L^2.7
^V1|||F …
OBX|2|SN|64084-7^M TB IGNF bckgrd cor Bld-aCnc^LN^DEXQE^TB1 Ag minus Nil Result^L^2.63^U||^0.62|[IU]/mL^international unit per milliliter^UCUM
||||F …
OBX|3|SN|88517-8^M TBIFN-g CD4 CD8 bckgrd cor Bld-aCnc^LN^DEXQF^TB2 Ag minus Nil Result^L^2.63^U||^1.64|[IU]/mL^international unit per milliliter^UCUM
|||||F …
OBX|4|SN|71774-4^Mitogen IGNF bckgrd cor Bld-aCnc^LN^DEXQG^Mitogen minus Nil Result^L^2.63^U||^3.84|[IU]/mL^international unit per milliliter^UCUM
|||||F …
OBX|5|SN|71776-9^Gamma interferon background Bld EIA-aCnc^LN^DEXQH^Nil Result^L^2.63^U||^5.86|[IU]/mL^international unit per milliliter^UCUM
|||||F …
SPM|1|…

Sample HL7 message for T-SPOT.TB

MSH|^~\&|
… SFT|…
PID|1|…
ORC|RE|MM0037-18085 Placer_LIS^2.16.840.1.113883.3.2.12.1.99^ISO|C626069565^Filler Order Number^2.16.840.1.113883.3.2.12.1.1^ISO|…
OBR|1| MM0037-18085 Placer_LIS^2.16.840.1.113883.3.2.12.1.99^ISO|C626069565^Filler Order Number^2.16.840.1.113883.3.2.12.1.1^ISO|74281-7^M TB IGNF+spot Pnl Bld^LN^ TSPT^TSpot test^L^^U|…
OBX|1|SN|74280-9^Mitogen IGNF.spot count Bld^LN^MitPC^Mitogen IGNF Positive Control^L^2.63^U||^7|{#}^number^UCUM|||||F …
OBX|2|SN|74279-1^IGNF neg cntrl Bld^LN^IGNFNC^IGNF Negative Control^L^2.63^U||^7|{#}^number^UCUM|||||F …
OBX|3|SN|74278-3^M TB IGNF.ESAT-6 Ag Bld^LN^ESAT6^IGNF ESAT 6Ag^L^2.63^U||>^16|{#}^number^UCUM|||||F …
OBX|4|SN|74277-5^M TB IGNF.CFP10 Ag Bld ^LN^CPF10^IGNF CFP10Ag^L^2.63^U||>^16|{#}^number^UCUM|||||F …
OBX|5|CE|71773-6^M TB IGNF Bld Ql^LN^IGNFQl^IGNF Interpretation^L^2.63^U||10828004^Positive^SCT||Negative|A^Abnormal^HL70078^A^Abnor mal
^L^2.7^V1|||F …
SPM|1|…